K123371

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JAN 08 2013

510(k) Premarket Notification – AlignRT Plus

510(k) Summary

The information below is provided for the modifications to AlignRT following the format of 21 CFR 907.92.

Submitter: Vision RT Ltd.
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Date Summary was prepared 25th October 2012

Name of the Device:	**AlignRT Plus**
Trade/Proprietary Name:	AlignRT Plus
Common or Usual Name:	Patient Positioning System
Classification Name:	Accessory to Medical charged-particle radiation therapy accessories, 90IYE, (per 21 CFR section 892.5050)

Predicate Device to claim substantial equivalence

Vision RT AlignRT (K052682)

Vision RT GateCT-RT (K072171)

Description of Device:

AlignRT Plus system is a combination of the predicate devices AlignRT (K052682) and GateCT-RT (K072171). It is a video-based three-dimensional (3D) surface imaging system, which is used to image the skin surface of a patient in 3D before and during radiotherapy treatment. The system consists of advanced software, a computer workstation, and one, two or three 3D camera units (each camera unit comprising a stereo pair of sensors to allow 3D surface reconstruction). The system is non-invasive, does not require the use of body markers and produces no ionizing irradiation during the imaging process.

AlignRT Plus is also able to perform both respiratory synchronised CT imaging and treatment delivery. In both instances, the system acquires a gated 3D surface model of the patient. User selected points are then tracked in real time in order to provide gating and position monitoring signals.

Real-time imaging and surface matching of the patient is possible during both setup and the treatment delivery to determine any patient movement. During treatment delivery, AlignRT Plus is also able to withhold the beam automatically, should the patient move outside user-defined tolerances.

Patient contour data may be extracted from surface data acquired by the system and exported for the purpose of treatment planning by radiotherapy professionals.

AlignRT Plus may be calibrated directly to the treatment beam isocentre using an optional custom designed calibration phantom and image processing software. It can analyse MV and kV digital imaging data acquired by other cleared devices. This in turn assists the user in performing quality assurance on MV, kV imagers, room lasers and the treatment couch.

The AlignRT Plus system includes the optional Head Adjuster for cranial treatments to allow for the manual, fine correction of pitch, roll and yaw in the patient's head position.

Precise isocenter calibration and the optional Head Adjuster provide improved frameless Stereotactic Radiosurgery (SRS).

Intended Use Statement:

The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocentre, and to withhold the beam automatically during radiation delivery. For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations. AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning. AlignRT Plus can be calibrated directly to the treatment beam isocentre and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the treatment couch. AlignRT Plus is indicated for use during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.

Summary of the Technological Characteristics:

The Substantial Equivalence Comparison Table shown below provides a comparison of the technological characteristics of AlignRT Plus to those of the predicate device:

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510(k) Premarket Notification – AlignRT Plus

	PREDICATE DEVICE 1	PREDICATE DEVICE 2	NEW DEVICE
DEVICE NAME	Vision RT's AlignRT (K052682)	Vision RT's GateCT-RT (K072171)	AlignRT Plus
MANUFACTURER	Vision RT Ltd	Vision RT Ltd	Vision RT Ltd
Indications for Use	The AlignRT system is used to position patients at the isocentre of the linear accelerator for radiation therapy procedures. Patient contour data can be extracted and exported from the acquired data for the purpose of treatment planning.	The GateCT-RT system is used to obtain tracking of the subject's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. It can be also used, either independently or in conjunction with Vision RT's AlignRT (K052682), to monitor the patient position during the image acquisition, simulation and treatment and to disable the radiation beam automatically.	The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocenter, and to withhold the beam automatically during radiation delivery. For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations. AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning. AlignRT Plus can be calibrated directly to the treatment beam isocenter and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the treatment couch. AlignRT Plus may be used during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.

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	PREDICATE DEVICE 1	PREDICATE DEVICE 2	NEW DEVICE
Principles of operation	Video based imaging of 3D skin surface data using surface matching software.	Video based imaging of 3D skin surface data using surface matching software.	Video based imaging of 3D skin surface data using surface matching software. Image processing of radiographic image data.
Target Population	Any individual (adult or child) undergoing radiotherapy.	Any individual (adult or child) undergoing radiotherapy.	Any individual (adult or child) undergoing radiotherapy
Materials	PC workstation, cables, video cameras.	PC workstation, cables, video cameras.	PC workstation, cables, video cameras. Block Polystyrene (calibration phantom), carbon fibre laminate material (head adjuster) which is substantially equivalent to the cleared Bionix (K100691) device..
System Performance and Accuracy	Sends computed coordinates to treatment couch. System accuracy: Errors along each of 3 axes of treatment: max mean: 0.27mm; max std dev: 0.65mm.	Tracks respiratory signal from imaged surface data and sends to CT (4D CT) or to Linac or imaging device (gating). Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing cycles.	Positioning accuracy: Target registration errors (as measured using calibration phantom) < 1mm for all couch angles. Respiratory tracking: Tracks respiratory signal from imaged surface data and sends to CT (4D CT) or to Linac or imaging device (gating). Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing cycles.
Biocompatibility	No contact with patient	No contact with patient	No direct contact with patient. Indirect contact with Head adjuster. This is made out of carbon fibre laminate material which is substantially equivalent to the cleared Bionix (K100691) device.

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510(k) Premarket Notification – AlignRT Plus

	PREDICATE DEVICE 1	PREDICATE DEVICE 2	NEW DEVICE
Mechanical Safety	Cameras are ceiling mounted and do not contact patient or user	Cameras are ceiling mounted and do not contact patient or user	Cameras are ceiling mounted and do not contact patient or user. Head adjuster is clamped to the treatment couch through universal base plate.
Anatomical treatment sites	Entire body surface	Anywhere one encounters the effects of respiratory motion. These areas include, but are not limited to, the lung, breast, liver, pancreas, kidney and organs in the pelvis region, such as the prostate.	Entire body surface.
Human factors	Imaging process is fully automatic as is estimation of new couch position; 3D visual display provided to show any discrepancy in patient position	User selects tracking point(s) during first session. This is detected automatically during subsequent sessions. Tracking of the respiratory signal is fully automated. Thresholds for gating are selected manually via software. Motion and irregular breathing are detected automatically.	Imaging process is fully automatic as is estimation of new couch position; 3D visual display provided to show any discrepancy in patient position. For respiratory tracking, user selects region of interest or tracking point(s) during first session. These are detected automatically during subsequent sessions. For cranial treatments, a manual head adjuster may be used by turning designated dials to provide fine corrections for pitch, yaw and roll rotations in concert with real time visual feedback provided to the user by AlignRT Plus.
Optical pattern	Optical (near infra-red) pattern is projected to patient.	Optical (near infra-red) pattern is projected to patient.	Optical (near infra-red) pattern is projected to patient.

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510(k) Premarket Notification – AlignRT Plus

	PREDICATE DEVICE 1	PREDICATE DEVICE 2	NEW DEVICE
Compatibility with the environment and other devices	Cleared for use in hospital environments	For use in hospital and clinic environments	For use in hospital and clinic environments
General Electrical safety standards	met	met	met
EMC standards	met	met	met

AlignRT Plus has the same intended use and safety characteristics as the comparable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 8, 2013

Dr. Norman Smith
Chief Executive Officer
Vision RT Ltd., Dove House
Arcadia Avenue
LONDON, N3 2JU, UK

Re: K123371
Trade/Device Name: AlignRT Plus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 26, 2012
Received: November 1, 2012

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123371

Device Name: AlignRT Plus

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety